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1. Purpose/Policy

The purpose of this document is to describe procedures for the Medical Device Single Audit Program (MDSAP) to identify, document, implement, monitor and close Corrective Actions (CAs).

A Corrective Action (CA) procedure defines requirements for reviewing nonconformities; determining the cause of nonconformities; evaluating the need for action to ensure that nonconformities do not recur; determining and implementing action needed; updating documentation; recording the results of the investigation and of the action taken; reviewing the corrective action taken; and verifying the effectiveness of the action.

A Preventive Action (PA) procedure defines requirements for determining potential nonconformities and their causes; evaluating the need for action to

prevent occurrence of nonconformities; determining and implementing action needed; recording of the results of any investigation and of action taken; reviewing the preventive action taken; and verifying the effectiveness of the action.

2. Scope

This procedure applies to MDSAP work products, processes, services, and quality management system.

3. Definitions/Acronyms

Cause: An identified reason for the presence of a defect or problem. (ASQ-Quality Glossary)

Complaint: Any written, electronic, or oral communication that alleges deficiencies or expression of dissatisfaction related to MDSAP program processes, products, or services. This includes alleged deficiencies related to an Auditing Organizations as well as manufacturers. Complaints are also objections, errors, or nonconformities involving work quality, or failures to provide service or other requests of the customer including timeliness.

Correction: Action to eliminate a detected nonconformity. (ISO 9000:20005)

Corrective Action (CA): Action to eliminate the cause of a detected nonconformity or other undesirable situation. (ISO 9000:2005)

Nonconformity (NC): Non-fulfillment of a requirement. (ISO 9000:2005)
Note: The MDSAP defines “direct” and “indirect” nonconformities to establish priority for corrective actions.

Nonconformity Report (NCR) Form: Form used to document a nonconformity, and, when applicable, to initiate corrective action(s), and to document the investigation, implementation and effectiveness of a CA. The NCR Form may refer to the location of records associated with the NCR (e.g. Investigation Report).

Preventive Action (PA): Action to eliminate the cause of a potential nonconformity or other undesirable potential situation. (ISO 9000:2005)

4. Authorities/Responsibilities

Regulatory Authority Council (RAC): As necessary, the RAC reviews corrective and preventive actions that have been brought to their attention by the MDSAP QMS management representative. It is recommended that the RAC reviews the CA/PA system during management review meetings at least

once a year.

Regulatory Authority Corrective Action (RA/CA) Contact: The RA/CA Contact will review the nonconformity to determine if the issue should be assigned for corrective action to the CA Assignee or closed with a correction. If a corrective action is required, the RA/CA Contact will assign the nonconformity to a CA Assignee within their organization. Each Regulatory Authority must designate an RA/CA Contact.

CA/PA Administrator: The CA/PA Administrator will enter nonconformities into the Corrective Action (CA) database and periodically perform a quality review of the contents of the database. The CA/PA Administrator is also responsible for the routine routing and management of corrective actions. The CA/PA Administrator will assign an identified nonconformity to the Corrective Action Contact designated by the Regulatory Authority for the affected country/region.

CA Assignee: The CA Assignee is responsible for developing and tracking corrections and corrective actions, and to report progress to the CA/PA Administrator and the RA/CA Contact. Any member of the MDSAP may serve as a CA Assignee.

MDSAP QMS Management Representative: Holds periodically reviews of the CA/PA System and communicate with RAC if any discrepancies are encountered. Follows up with each MDSAP Quality Management System Site Representative as necessary.

CA/PA System Manager: The RAC Chair is assigned this role. The CA/PA System Manager has overall responsibility for the CA/PA system management.

PA Assignee: The PA assignee is responsible for developing and tracking preventive actions and to report progress to the CA/PA Administrator. Any member of the MDSAP Team can be a PA Assignee. Refer to MDSAP QMS P0010 Preventive Action (PA) Procedure for further information on preventive actions.

5. Procedures

5.1 Identifying and Reporting Nonconformities

Any MDSAP personnel or program participant may identify nonconformities as a result of: (1) the investigation of complaints (both internal and external to MDSAP): (2) process failures; (3) internal audits; (4) management reviews; or (5) any other source. The individual reporting an identifying nonconformity should electronically document the event using the form MDSAP QMS F0013.1 Concern and Resolution Form and forward the form by email to the CA/PA Administrator for assignment.

The CA/PA Administrator will use the location of a complaint / nonconformity to determine and assign an appropriate RA/CA Contact. The RA/CA Contact will evaluate and identify those requirements that have a predetermined direct impact or indirect impact on MDSAP performance as a means of giving prioritizing responses to nonconformities. The RA/CA Contact may close a NC with a correction and refer the event back to the CA/PA Administrator. For example, a human error in transcribing information for nonconformity into a database, or into a report, is often a one-time oversight not requiring CA.

The RA/CA Contact must document on the Concern and Resolution form an evaluation of the NC and whether or not a Corrective Action (CA) is required. Reminder: a CA is taken to prevent recurrence, a PA is taken to prevent occurrence.

If a Corrective Action is required, the RA/CA Contact will assign the nonconformity to a CA Assignee within his/her organization. When necessary, the RA/CA Contact may consult with the CA/PA Administrator to make this determination. Once a decision is made, the RA/CA Contact will email the CA/PA Administrator documenting the reasons for requiring, or not requiring, CA for the event. If the CA/PA Administrator accepts the proposal for CA, and an entry in the CA/PA system, the e-mail will contain the target completion date along with the CA Assignee who will be responsible for the CA.

Once a CA Assignee has received notification of an open CA, the assignee becomes the owner of the issue. The assignee may request assistance from other MDSAP members to identify, implement, and verify the effectiveness of appropriate corrective actions. The CA/PA assignee should communicate to the CA/PA Contact and Administrator, any difficulties encountered, or additional resources required to progress corrective actions to completion. Once assigned a CA, the CA Assignee must determine and document the following information using MDSAP QMS F0013.1 Concern and Resolution (NCR) Form.

Nonconformity description: The CA/PA Assignee should record a description of the NC with factual and precise language that clearly states the requirement, enables the reader to comprehend the non-fulfillment of a requirement, and references information to support the claim. The information presented should be an accurate representation of the records, samples and procedures reviewed, as well as interviews conducted. The CA/PA Assignee may combine multiple instances of the non-fulfillment of a requirement into a single nonconformity unless the instances originate or relate to different aspects of a requirement.

5.2 Risk Assessment

Prior to the investigation of any nonconformity, the CA assignee must identify

the hazards (potential sources of harm) associated with the nonconformity and estimate the risk(s) associated with those hazards. These risk assessments may indicate the nonconformity is likely to, or has caused, a systemic failure within the MDSAP quality management system or is likely to cause, or has caused, significantly inaccurate work products which could, or may have, led to poor decisions or other adverse actions. The CA assignee should also perform a risk assessment on the proposed corrective action to ensure that any introduced hazards are of an acceptable risk.

Any investigation and subsequent corrective action should be commensurate with the risk(s) posed by the nonconformity.

Risk Analysis Techniques: Techniques for the assessment of risk include; Fault Tree Analysis (for hazard identification) and Failure Mode and Effects Analysis (for the estimation and evaluation of risk), and many others. Risk management standards express risk using two quantities: 1) the magnitude or severity of the harm that may arise because of the nonconformity and 2) the probability of occurrence/reoccurrence of the harm due to the nonconformity. The CA Assignee is to document the assessed risk from the nonconformity on the Concern and Resolution Form. The assessment must incorporate the two quantities noted above.

Please refer to QMS MDSAP P0004 Risk Management Procedure for guidance on Risk Management.

5.3 Investigation of Nonconformities

The CA / PA Assignee must investigate the nonconformity to determine the cause before an appropriate CA is developed. The investigation should build upon any existing analysis, evaluation and investigation. Some of the more common tools and techniques used in cause investigation include:

- The 5 Why's Analysis: The goal of this analysis is to trace the chain of causality in direct increments from the effect through any layers of abstraction to a cause that still has some connection to the original problem. For example, if the problem is that Auditing Organizations are submitting incomplete reports to the MDSAP Team, the CA Assignee would ask: 1) Why? – An example answer may be "the web-based interface is too complicated." Then the CA Assignee would ask: 2) Why? – An example answer to that is "the interface has similar text field entry requirements in multiple locations." The CA Assignee would then ask: 3) Why? This would continue in order to drill down to the main cause of the problem. This may require more than 5 Why's.

- Pareto Analysis: This type of analysis is useful where many possible courses of action are possible. The analysis results are arranged on a

Pareto Chart for visual representation. Generally, Pareto Analysis can help to identify 20% of the causes of 80% of the problems within a system. Please refer to ASQ.org or other reference material for more information regarding Pareto Analysis and Charting.

- Fishbone/Ishikawa Cause and Effect Diagrams: These are diagrams which show the causes of a specific event. An investigator may group causes into major categories to identify the sources of variation. These categories may include: 1) People, 2) Methods, 3) Machines (computers, etc), 4) Materials, 5) Measurements and 6) Environment. Creation of a diagram which evaluates the possible contribution of each of these categories will usually reveal the cause of the nonconformity.

These tools are examples. Other tools are available and may be used as appropriate.

The CA/PA Assignee should describe the cause of a NC after a full investigation has occurred. The investigation and cause must be documented on the MDSAP QMS F0013.1 Concern and Resolution Form. As part of the investigation of the cause of the nonconformity, the risk of the nonconformity as well as the risk of the recurrence of the nonconformity should be determined and documented on the Concern and Resolution Form. The CA/PA Assignee must initiate a CA if the cause of a NC cannot be determined (versus only performing a Correction). The CA/PA Assignee should not implement CA until the cause of the nonconformity has been determined.

If the CA/PA Assignee identifies a need for Preventive Action (PA) during the investigation into root cause, please see the MDSAP QMS P0013 Preventive Action Procedure.

5.4 Implementing Corrective Actions

When the CA Assignee has fully described the NC and investigation has determined the cause a correction or corrective action may be determined.

- ***Correction of nonconformity:*** Explain in detail how the identified nonconformity will be, or has been, corrected. Before initiating a correction, the CA Assignee must consult with the CA/PA Contact on the proposed correction. A Correction Action (CA) does not always follow a Correction. (See next step).

- ***Determination of Corrective Action (if required):*** The CA Assignee must determine and fully document the cause of the nonconformity prior to any CA to prevent a recurrence of the NC. Full documentation of the CA taken is required. When developing a CA, the CA Assignee

must fully document all actions taken to resolve the systemic problems which led to the nonconformity. A simple retraining of staff or revision of a procedure may not be adequate.

The CA Assignee must document or refer to a list of action items on the NCR Form before implementing corrective action. These may include:

- A detailed description of the implementation of the action
- Review of any applicable regulatory requirements
- Roles and responsibilities for execution of action items
- Identification of the necessary resources (e.g. IT infrastructure, financial, etc.)
- Verification and/or validation protocols of the action with acceptance criteria
- Timeline for implementation
- Method for the determination of effectiveness with acceptance criteria
- Identify the starting point of monitoring and end point of correction and/or corrective action

NOTE: The CA Assignee **must** consult with the RA/CA Contact regarding the adequacy of the proposed CA before taking any action.

- ***Verification and Validation of Action to be taken:*** Where possible, the proposed Corrective Action should be verified and validated before implementation. These activities should ensure that the proposed action will prevent recurrence. Validation and verification activities and subsequent results must be documented on the Concern and Resolution Form.

  Examples of items to be considered when planning verification / validation activities include:

  - Does the action eliminate the identified cause?
  - Does the action cover all affected work products or processes?
  - Does the action adversely affect the work products or processes?
  - Is it possible to complete the action in a timely manner?
  - Is the action commensurate with the degree of risk previously established?
  - Has the action introduced new risks or nonconformities?

- ***Results of action taken:*** A description of the CA taken as well as the results must be recorded on the Concern and Resolution Form.

- ***Determining effectiveness of Corrective Action:*** The CA Assignee must verify that the CA has been effective in mitigating the cause of the nonconformity before the CA can be successfully completed. The effectiveness verification must be documented on the Concern and Resolution Form. Some questions to keep in mind when evaluating the effectiveness of the CA include:

    - Was the problem captured accurately and completely?
    - Has the extent of the problem been captured?
    - Was the cause effectively identified and mitigated?
    - Was the CA completely defined, planned, documented, verified, validated and implemented as intended?

5.5 Timeframes

All CA/PAs will be opened with a target completion date of ***60*** days; however, it is understood that some actions may take longer. When the CA/PA assignee anticipates that a Corrective Action or Preventive action will take longer than 90 days, the CA/PA assignee should notify both the RA/CA Contact and the CA/PA Administrator by e-mail and describe the reason for the extended timeline. The CA assignee is responsible for updating the CA/PA database with target completion dates.

5.6 Closeout

When the CA/PA Assignee has successfully implemented all Corrective Actions and verified their effectiveness, the CA assignee will notify the CA/PA Contact and CA/PA Administrator by e-mail.

5.7 Regulatory Authority Council (RAC) Review of CA/PA During Management Review

The RAC will hold reviews of Corrective Actions and Preventive Actions that are brought to their attention by the MDSAP QMS Management Representative on as “as-needed” basis. The CA/PA system will be reviewed by the RAC during the management review meetings convened by the RAC.

5.8 MDSAP QMS Management Representative Review of CA/PA

The MDSAP QMS Management Representative will hold periodic reviews of the CA/PA system.

The topics for the reviews will include:

- Review of all open CAs and/or PAs, including proposed timeline for completion and any resources required to complete CAs and/or PAs.
- Review of all CAs and PAs closed during the preceding quarter.
- Review of the CA/PA database and SOP, including recommended

improvements and changes.

At least two weeks prior to the MDSAP QMS Management Representative review of CA/PA, the CA/PA Administrator will send an e-mail to all CA and PA Assignees with open CAs/PAs requesting that they provide up-to-date information regarding the status of their CAs/PAs.

Any discrepancies will be communicated to the RAC and the MDSAP QMS Site Representative for follow up.

6. Forms

MDSAP QMS F0013.1 Concern and Resolution Form

7. Reference Documents

Conformity Assesment - General Requirements for Accreditation Bodies Accrediting conformity assesment bodies. (2004). *ISO/IEC 17011:2004(E)*. International Organization for Standardization (ISO).

Quality Managment System - Medical Devices - Guidance on Corrective Action and Preventive Action and related QMS Processes. (2010, November 4). Global Harmonization Task Force Study Group 3.

Medical Devices - Application of Risk Management to Medical Devices. (n.d.). *BS EN ISO 14971:2012*. International Organization for Standardization (ISO).

Medical Devices-Quality Management Systems - Requirements for Regulatory Purposes. (n.d.). *ANSI/AAMI/ISO 13485:2003/(R)2009*. Association for the Advancement of Medical Instrumentation.

8. Document History

VERSION NO.	VERSION DATE	DESCRIPTION OF CHANGE	AUTHOR NAME/PROJECT MANAGER
001	2013-07-15	Initial Release	Kenneth C. Millen
002	2015-01-21	Procedure was revised to accommodate the whistleblower policy and process and changes with QMS. Section 7. Reference removed HC Guidance	MDSAP Team

003	2016-01-27	Replaced under Section Form: QMS F0006.1 NCR and QMS F0009.1 CAPR with QMS F0013.1 Concern and Resolution Form	MDSAP Team

Version 003

Approval

Signature on file Date: 2016-01-27

Approved: Team Lead FDA MDSAP